REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed April 14, 2009. Claims 21, 22, 24-26 and 31-45 were pending and rejected in view of cited art.[1] Claim 43 is canceled and claims 21 and 24 are amended. Claims 21, 22, 24-26, 31-42, and 44-45 are now pending in view of the above amendments.[2]

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

B. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office Action rejected claim 21 under 35 U.S.C. § 112, second paragraph as being indefinite for using the phrase "common distal ends" because "common" has various definitions. Applicant respectfully asserts that a claim term may have more than one definition and still satisfy the definiteness requirement of 35 U.S.C. § 112, second paragraph. However, by this amendment the phrase "common distal ends" has been removed from claim 21, rendering the rejection moot.

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[1] Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

[2] Support for the claim amendments and/or new claim(s) can be found throughout the specification and/or drawings as originally filed.

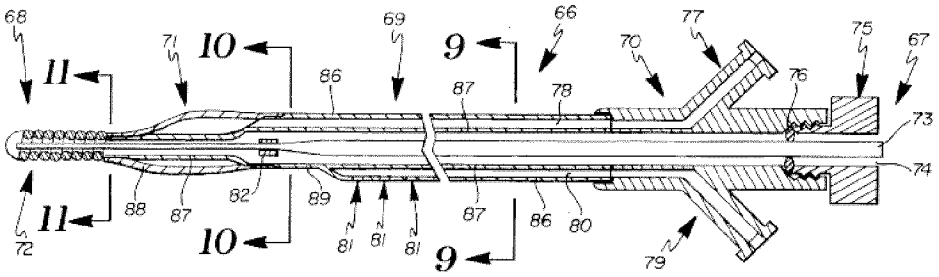
C. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 21, 22, 24, 31-33, 36, and 41-45 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,626,601 (*Gershony*).

Applicant traverses the Examiner's rejection for obviousness on the grounds that the references – either individually or in combination – fail to teach or suggest each and every element of the rejected claims. Applicant further asserts that the cited references fail to provide any teaching, suggestion, or apparent reason for modification to achieve the device claimed.

Gershony discloses vascular sealing device including a shaft (69) having "a balloon portion 71 disposed at the distal end of the shaft 69" (Col. 6, lns. 37-38). The shaft (69) further includes a "hemispherical inflation lumen 78 which extends into the shaft 69 and balloon 71" (Col. 6, lns. 60-62). A "hemispherical injectate lumen 80 ... extends into the shaft 69 to a plurality of injectate egress apertures 81... The injectate lumen is formed between the outer shaft wall 86 or layer and an inner shaft wall 87" (Col. 7, lns. 9-15). "A procoagulant is injected through the injectate port 79, into the injectate lumen 80, and is released at the puncture site ... through the injectate apertures 81" (Col. 7, lns. 17-20).



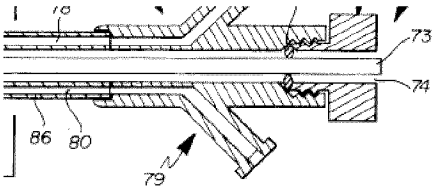
In contrast, claim 21 recites, in combination with other elements, a "device comprising: a housing comprising an outer tube and an inner tube, the inner tube having a lumen and a plurality of lateral openings in fluid communication with the outer tube, the lumen being configured to receive a volume of blood and a blood congealing agent to form the autologous plug; a closure element positioned within the lumen and configured to be inserted from the lumen into the puncture tract and to isolate the volume of blood admixed with the blood congealing agent from the vessel during formation of the autologous plug; and a plunger disposed for translation within the lumen to extrude the autologous plug formed within the lumen.

The Office Action asserts that the lumen (80) and the lateral openings (81) correspond to the "inner tube having a lumen and a plurality of lateral openings in fluid communication with the outer tube" and that the introducer sheath (61) corresponds to the outer tube (Office Action, page 3).

Applicant notes at the outset that the introducer sheath (61) of *Gershony*, though it appears to be present during part of the procedure for which the device is used, is not part of the housing of the disclosed device and may not be considered as the outer tube of "a housing comprising an outer tube and an inner tube," as recited in claim 21. Furthermore, *Gershony* fails to disclose "a closure element positioned within the lumen and configured to be inserted from the lumen into the puncture tract and to isolate the volume of blood admixed with the blood congealing agent from the vessel during formation of the autologous plug," where the lumen is characterized as the lumen (80) as asserted in the Office Action. Closure of a puncture is provided by the balloon (71) in the device of *Gershony* (*See* Col. 5, lns. 60-67). There is therefore no teaching, suggestion, or apparent reason to provide a closure element within the lumen (80), which already has a specific function, namely, to facilitate procoagulant injection (Col. 7, lns. 17-20).

A closure element positioned within the lumen 80 further could not be sized to have the attributes recited in claim 21 and still be positioned within the small hemispherical lumen (80). The lumen (80) is hemispherical in shape and includes a row of small openings (81) along the length thereof as is apparent from Figure 8 (reproduced above). There is no teaching, suggestion, or apparent reason for modification of *Gershony* to position "a closure element" having the attributes recited in claim 21 within the lumen (80). There is further no means for such a closure element to be "inserted from the lumen into the puncture tract," as recited in claim 21, through the small lateral openings (81) if the lumen is considered to be the lumen (80) of *Gershony*, as asserted in the Office Action. Any reason to modify *Gershony* to overcome these deficiencies is not apparent from *Gershony*, but rather is only apparent based on improper hindsight in view of Applicant's own disclosure.

The Office Action also asserts, without citation of a reference, that it would have been obvious "to modify the device of Gershony et al. by connecting a syringe to the injectate port of Gershony et al...." (Office Action, page 4). Applicant respectfully disagrees. As is apparent in



Figures 8 and 9, the injectate port (79) has a bent shape and the lumen (80) has a hemispherical cross section. It is not apparent from *Gershony* how a syringe plunger could be combined with these structures to achieve the device recited in claim 21. There is further no teaching, suggestion or apparent reason why the device of *Gershony* could or should be modified to accommodate a syringe plunger.

Any modification or reason for modification is apparent only based on improper hindsight in view of Applicant's own disclosure. The bare conclusory statement that "it would have been obvious ... to modify the device of Gershony et al." is insufficient to establish a *prima facie* case of obviousness. MPEP 2141.III ("'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at 82.").

Claims 22, 24, 31-33, 36, and 41-45 are dependent on claim 21 and are therefore allowable for at least the reasons noted hereinabove.

In addition, with respect to claim 24, *Gershony* fails to disclose, teach, or suggest a device as recited in claim 21 "wherein the autologous plug formed in the lumen has a length and a form factor that causes the autologous plug to engage tissue surrounding the puncture tract to occlude the puncture tract after extrusion of the autologous plug by the plunger into the puncture tract."

As noted above, the Office Action has characterized the lumen 80 as the lumen of claim 21. As also noted above, the lumen (80) has a small hemispherical cross section and includes very small openings (81). *See* Figures 8 and 9. As shown in Figure 8, the lumen (80) and openings (81) are extremely small compared to the overall diameter of the shaft (69). As is apparent from Figures 5 and 6, the shaft (69) fits within a larger introducer sheath (61) positioned in the puncture tract. It would appear, therefore, that any plug extruded from the openings (81) would be much too small to satisfy the elements of claim 24 with respect to the puncture tract occupied by the introducer sheath (61). There is further no apparent reason to modify *Gershony* to remedy this deficiency. Any modification or reason for modification is only apparently based on improper hindsight in view of Applicant's own disclosure.

With respect to claim 32, the Office Action has cited Col. 2, lns. 29-39 as teaching a device "wherein the blood congealing agent is coated onto an interior surface of the lumen." Applicant respectfully asserts that the cited portion of *Gershony* fails to disclose, teach, or suggest any coating within the lumen (80), which the Office Action characterizes as the lumen of claim 32.

Claim 33 recites a device "wherein the blood congealing agent is introduced into the lumen through the plurality of lateral openings." Applicant notes that in the device of *Gershony* the opposite is true if the lumen of claim 33 is considered to be the lumen (80) as asserted in the Office Action. The procoagulant is introduced into the lumen (80) through the injectate port (79) and released through the openings (81). *See* Col. 7, lns. 17-20. The elements of claim 33 are therefore not shown in *Gershony*.

With respect to claim 41, as noted above, the introducer sheath (61) is not part of the device of *Gershony*, but rather is only present when the device is used. *See* Figures 5 and 6. *Gershony* much less discloses a device "wherein the inner tube is fixed relative to the outer tube," as recited in claim 41, where the outer tube is the introducer sheath (61) as asserted in the Office Action.

Claims 21, 25, 26, and 37-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication No. 2002/0072767 (*Zhu*) in view of U.S. Patent No. 5,545,178 (*Kensey*).

Kensey has been cited as teaching a pledget and thread (*see* Col. 8, ln. 60; Col. 9, ln. 35).

Zhu teaches a catheter (32) having a "sponge 80 extend[ing] circumferentially around the catheter main body 42, and ... arranged so that it can be slid longitudinally along the catheter 32" (Paragraph 49). "A push member is also arranged on the catheter distal of the sponge 80. The push member 84 comprises a body portion 86 and a proximal handle portion 88. An elongate lumen 90 is formed through the body portion 86... [T]he lumen 90 preferably encircles the catheter 32 so as to allow the push member 84 to slide relative to the catheter 32" (Paragraph 50). The body portion (86) and catheter (32) are positioned within retractor arms (72) (Paragraph 46). The retractor arms are "separated ... drawing surrounding tissue 96 from the wound w and creating a field 100 around the puncture wound w" (Paragraph 55).

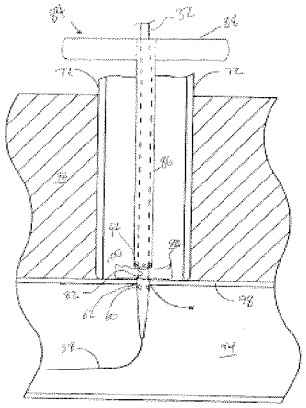


FIG. 6

The Examiner has characterized the retractor arms (72) as the outer tube and the body portion (86) as the inner tube as recited in claim 21 (Office Action, page 4). Applicant respectfully asserts that the retractor arms (72) are not a tube and therefore fail to satisfy these claim elements. Applicant further asserts that combining the pledget and thread of *Kensey* with *Zhu* fails to remedy this deficiency. Accordingly, a *prima facie* case of obviousness has not been established for at least this reason.

The Office Action states that *Zhu* fails to disclose a closure element as recited in claim 21, but that the pledget (38) and thread (42) of *Kensey* satisfy this element (Office Action, page 5). Applicant respectfully asserts that there is no teaching, suggestion, or apparent reason to combine these references to achieve the claimed device. In particular, as noted above, *Zhu* teaches a device wherein a sponge (80) is positioned outside of the catheter (32) and is pushed along the catheter (32) by the body portion (86) (Paragraph 50). At no point during the use of the device of *Zhu* is the sponge (80) positioned within the body portion (86). It is not apparent from either of the cited references how or why the pledget and thread of *Kensey* should be used instead of the sponge (80) – much less be positioned within the body portion (86). *Zhu* in fact teaches against such a modification inasmuch as the device of *Zhu* is used by first positioning the catheter (see Paragraph 53) in a puncture and then advancing the body portion (86) and sponge (80) over the catheter (see Paragraph 57). A pledget and thread as taught by *Kensey* positioned in the body portion 86 would be displaced proximally by the catheter (32) and could not access the puncture site.

Zhu and *Kensey*, taken alone or in combination, therefore fail to teach, suggest, or provide an apparent reason for modification to achieve "a housing comprising an outer tube and an inner tube ... [and] a closure element positioned within the lumen of the inner tube and configured to be inserted from the lumen into the puncture tract and to isolate the volume of blood admixed with the blood congealing agent from the vessel during formation of the autologous plug...," as recited in claim 21, if the inner tube and lumen is considered to be the body portion (86).

Claims 25, 26, and 37-40 are dependent on claim 21 and are therefore allowable for at least this reason.

Claims 34 and 35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Zhu* in view of *Kensey* and further in view of U.S. Patent No. 6,391,037 (*Greenhalgh*). *Greenhalgh* has been cited as teaching platinum and thermo-resistive wires. Notwithstanding this teaching,

Greenhalgh fails to remedy the deficiencies of *Zhu* and *Kensey* noted above with respect to claim 21, upon which claims 34 and 35 depend. Accordingly, a *prima facie* case of obviousness has not been established with respect to claims 34 and 35.

D. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 14th day of August, 2009.

Respectfully submitted,

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